

REMARKS

Applicants respectfully request reconsideration and allowance.

Applicants respectfully request the Examiner to enter the amended claims. First, amended claims 11 and 20 present language consistent with the characterization of claim 11 in the December 27, 2003 Amendment at page 5. There appears to be a no new issue. Second, there does not appear to be new matter because the amended claims find support in the specification throughout, including the original claims. Amended claims 1 and 20 are presented consistent with the specification, such as at page 13, and illustrated in Fig. 4B. Amended claim 14 corrects the spelling of layer. Amended claim 15 presents an amended dependency to assure better antecedent basis for a covering layer. Amended claim 16 corrects the spelling of terephthalate. Amended claims 1, 20 and 25 also include amending "tape type patch" to delete 'type'. Third, the objection to the drawings under 37 C.F.R. 1.83(a) should be reconsidered and withdrawn. Fourth, Applicants respectfully suggest that the formality rejection under Section 112 should be overcome too. Fifth, Applicants acknowledge the Examiner's constructive comments and have endeavored to responsibly address them with the amended claims presented herewith.

Applicants' representative acknowledges the Examiner's courtesy in during telephone discussions concerning this application, despite her being on leave at the time. The Examiner's diligence is very much appreciated. Applicants' representative understands from the discussions that the claims as presented above should obviate concerns over matters of form and that any formality rejections would be favorably reconsidered.

Applicants do, however, earnestly but respectfully submit that the claims are also amenable to being allowed over the art as applied in the Office Action noted on page 1 of this Amendment.

Claims 11-13 and 19 define novel, unobvious inventions under 35 U.S.C. §103(a) over JP S57-111822 and/or JP S55-134822 and/or JP S56-60730 in view of JP S61-108257 and Tomiuolo (U.S. Patent No. 5,782,786).

Applicants respectfully traverse. Applicants have endeavored to address the rejection but respectfully request some leniency inasmuch as the multiple "and/or" expressions unfortunately made the basis for rejection somewhat muddy and thus there might be a chance that an aspect of a rejection was not adequately addressed in this Amendment.

An embodiment of the present invention according to claim claim 11 concerns a roll type external patch (transdermal patch) in which a tape patch having a tape type support, adhesive layer (with a medicine) laminated on all over one side of the tape type support is wound around a dispenser core with covers at both ends thereof. Further, in the roll type transdermal patch, a plurality of tear off cutting lines are provided in the tape patch in a direction crossing a longitudinal direction thereof, and the tear off cutting lines are located in positions at which the adhesive layer exists and the tear lines are in a direction perpendicular to a side surface of the tape type support.

The present invention according to claim 20 is directed to a roll type patch that may have three layers.

None of the references would appear to suggest the elements of claims 11-13 and 19.

The primary reference admittedly do not disclose and therefore would not have taught the material or tear lines to a person of ordinary skill in the art. "JP S57-111822 and/or JP S-134822 and/or JP S56-60730 do not disclose the specific material and tear off cutting lines." Office Action, page 4.¹

¹ The abstract and drawings to JP-S57-111822 apparently does not disclose a pair of side covers. Side covers are *not* consistent with what is depicted in the Figures. JP S56-60730 refers to an adhesive plaster having what appears to be notched edges. The JP '730 reference would not

The secondary reference to Tomiuolo would not have been combined with any of the primary references, and even if it was, the missing teachings in the primary references would not have been supplied by the Tomiuolo reference. The Tomiuolo reference does not describe the structure of claim 11 or its dependent claims and therefore whether or not it might refer to perforation lines 15 is beside the point. Selecting a reference to tear lines would not have motivated a person of ordinary skill in the art towards the combination of claim 11 or claim 20, nor to their respective dependent claims.

The other secondary reference to JP-S61-118527 would not have been combined with any of the "and/or" primary references and with the Tomiuolo reference, and even if, *arguendo*, it was combined, the missing teachings in the primary references and in Tomiuolo would not have been supplied by JP-S61-118527. The secondary JP '527 reference apparently refers to a case for a tape that is provided with a tape cutter. The JP '527 reference does not appear to refer to lines, perforated or not, in a roll type patch tape, nor is speculation a substitute for what is missing in the JP '527 reference. The '527 reference apparently would not have been combined with a reference that neither illustrates nor apparently contemplates side covers, such as JP S57-111822.

Furthermore, as to selection of proper materials for a roll type tape of the invention, the Office Action offers a citation to a court case decided before the U.S. Supreme Court decision of Graham v. John Deere, 383 U.S. 1 (1966). There are no *per se* rules of obviousness that supplant the factual inquiry mandated under 35 U.S.C. 103(a). The Applicants also respectfully point out that the inquiry under 35 U.S.C. §103 in the Office Action should have adhered to the statute and the controlling legal authority of the

have suggested tear off cutting lines being located at positions so as to extend through the tape type support and the adhesive layer, wherein the tear off cutting lines are in a direction perpendicular relative to the side surface(s) of the tape type support, since the reference does not show lines, perforated or not, as conceded in the Office Action. The JP S55-134822 reference seems to be a variation on the theme of JP S56-60730 and it too appears neither to disclose nor to describe tear off cutting lines being located at positions so as to extend through the tape type support and the adhesive layer, wherein the tear off cutting lines are in a direction perpendicular relative to the side surface(s) of the tape type support, since the reference does not show lines, perforated or not, as conceded in the Office Action.

United States Supreme Court in the Graham case (MPEP §706.02(j) and MPEP §2141 "35 U.S.C. 103; The Graham Factual Inquiries"), and omitting the reference to the Graham case in the the Office Action seems rather telling. Rote reliance on the Lehsin case should be reconsidered and withdrawn. Applicants respectfully request the Examiner to supply evidence such as an Examiner's Declaration and references in the event reliance on Leshin is not reconsidered and withdrawn. Applicants respectfully submit the rejection should be reconsidered and withdrawn.

Claim 18 defines a novel of unobvious invention under 35 U.S.C. §103 "over the references applied above with respect to claim 11, further in view of Official Notice."

Applicants submit the record lacks evidentiary support for the alleged Official Notice.² In re Alhert, 424 F.2d 1088 (CCPA 1970) ("We know of no case in which facts judicially noticed comprised the principal evidence upon which a rejection was based or were of such importance as to constitute a new ground of rejection when combined with the other evidence previously used.") It is respectfully suggested that the Examiner withdraw the allegation or submit an Examiner's Declaration.

Applicants also respectfully request reconsideration and withdrawal of the now oft-cited "routine experimentation." It is neither a factual nor legal substitute for the legal-factual application required in an obviousness analysis under 35 U.S.C. 103(a). The CCPA, now the Federal Circuit, decisions, including the In re Antonie, 195 USPQ 6, 8 (CCPA 1977) decision, have long instructed:

"The PTO and the minority appear to argue that it would always be *obvious* for one of ordinary skill in the art *to try* varying *every* parameter of a system in order to optimize the effectiveness of the system even if there is no evidence in the record that the prior art recognized that particular parameter affected the result. As we have said many times, *obvious to try* is not the standard of 35 USC 103. In re Tomlinson, 53 CCPA 1421, 363 F.2d 928, 150 USPQ 623 (1966). Disregard for the unobviousness of the results of "obvious to try" experiments disregards the "invention as a whole" concept of §103, In re Dien, 54 CCPA 1027, 371 F.2d 886, 152

²In re Lee, 61 USPQ 2d 1340 (Fed. Cir. 2002).

USPQ 550 (1967) and *In re Wiggins*, 55 CCPA 1356, 397 F.2d 356, 158 USPQ 199 (1968), and overemphasis on the routine nature of the data gathering required to arrive at appellant's discovery, after its existence became expected, overlooks the last sentence of §103. *In re Saether*, 492 F.2d 849, 181 USPQ 36 (CCPA 1974)."

It is respectfully submitted that the rejection be reconsidered and withdrawn.

Claims 11-16, 19-24 and 26 define novel, unobvious inventions the "over Admitted Prior Art on page 1 of the specification in view of Tomiuolo (U.S. Patent No. 5,782,786).

There is no admission as to the roll type transdermal patch roll of claim 11, nor as to side covers nor, for instance, tear off cutting lines.

None of the references discloses or suggests that the tear off cutting lines are located at positions which a adhesive layer is present and are positioned so as to be in a direction basically perpendicular to one side surface of the tape type support as indicated in independent claims 11 and 20. For instance, Tomiuolo discloses the provision of a perforation line 15, but the perforation lines are provided at a position where any absorbent pad does not exist (See Fig. 1). It would appear the other references neither disclose nor even suggest perforation lines. Accordingly, the claimed inventions would not have been suggested by the cited documents, even if there were admissions, which there are not.

Claims 17-18 and 25 define novel, unobvious inventions under 35 U.S.C. §103(a) "over the references applied above with respect to claims 11 and 20, further in view of Official Notice."

Even if, *arguendo*, the alleged combination of references and the factually naked Official Notice were considered, "[t]he modified reference does not disclose the width and spacing of the perforation slits." Office Action, page 6.

The Office Action nonetheless postulates "experiments" could determine "the proper width of the slit and the spacing between the slits." This assertion lacks a factual foundation since the JP references do not disclose the specific material and tear off cutting lines. Office Action, page 4.

Furthermore, the Office Action reports the rejection being based on an incorrect legal analysis lacking basis in the patent statute. The Office Action reports reliance on "routine experimentation" in contravention of 35 U.S.C. 103(a) (last sentence). Patent acquisition does not require any threshold level of effort. *See*, 35 U.S.C. § 103(a) (2000) ("Patentability shall not be negated by the manner in which the invention was made."); 35 U.S.C. § 103 Revision Notes and Legislative Reports, 1952 Notes ("[I]t is immaterial whether [the invention] resulted from long toil and experimentation or from a flash of genius."); Life Techs., Inc. v. Clontech Labs., Inc., 224 F.3d 1320, 1325 (Fed. Cir. 2000) (stating that "the path that leads an inventor to the invention is expressly made irrelevant to patentability by statute"); In re Cormany, 407 F.2d 900 (CCPA 1969) (acknowledging allegations of routine experimentation are not adequate for an obviousness rejection); In re Tomlinson, 363 F.2d 328 (CCPA 1966) (arguments by Examiner and Board that it would be routine experimentation "simply...begs the question"); and In re Fay, 347 F.2d 597 (CCPA 1965) (reversing rejection relying on routine experimentation, noting that the statute provides that patentability shall not be negated by the manner in which was made).

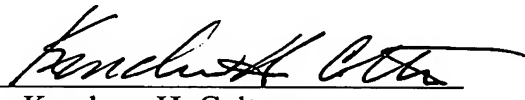
Applicants respectfully solicit a *personal* interview.

Appl. No. 10/049,162
Amdt. dated *July 29, 2004*
Reply to Office Action of January 29, 2004

Applicants have sought to address all matters in an effort to place their application in condition for an allowance. Applicants earnestly, but respectfully, request reconsideration and a favorable first action on the merits.

Respectfully submitted,

FITCH, EVEN, TABIN & FLANNERY

By: 
Kendrew H. Colton
Registration No. 30,368

Customer No. 42798

FITCH, EVEN, TABIN & FLANNERY
1801 K Street, NW - Suite 401L
Washington, DC 20006-1201
Telephone: (202) 419-7000
Facsimile: (202) 419 -7007